

## **REMARKS**

The pending non-final Office Action addresses and rejects claims 1-20. Independent claim 1 is amended herein. Support for the amendment can be found throughout the specification at, for example, paragraphs [0029] and [0044]. No new matter has been added.

### **Information Disclosure Statement**

The Examiner informs applicant that the Examiner has not been provided with copies of some of the references identified on Applicant's Information Disclosure statement submitted previously. Accordingly, Applicant submits herewith a Supplemental Information Disclosure Statement including copies of those references.

Additionally, Applicant also identifies on the Supplemental Disclosure Statement four references which have recently come to applicant's attention vis-à-vis a related European application.

### **Objections to the disclosure**

The disclosure is objected to for minor informalities.

The Examiner requests that paragraph [0001] be amended to update the current status of the parent application. The specification has been amended accordingly.

### **Nonstatutory double patenting**

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,6-8, 11,12, 14-20 and 27-30 of U.S. Patent No. 6,638,415("415 patent".)

Applicant has amended independent claim 1 and therefore submits that applicant as overcome this rejection with respect to claims 1-20. However, applicant agrees to submit a Terminal Disclaimer with respect to the term of Applicant's '415 patent in the event that the Examiner maintains this rejection once patentable subject matter has been found.

**Claim Rejections - 35 U.S.C. § 102**

The Examiner rejects claims 1-6,8-12 and 18-20 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,437,999 of Diebold et al. ("Diebold"). Applicant respectfully disagrees.

In order for Diebold to anticipate applicant's independent claim 1, Diebold must disclose each and every element of applicant's claim 1. Applicant respectfully submits that Diebold fails to teach all of the claimed elements.

Independent claim 1 as amended recites a device for detecting the presence or an absence of a redox reactive analyte in an aqueous sample comprising an electrochemical cell having one or more walls, the electrochemical cell comprising a sensing chamber, a first electrode, a second electrode, an aperture for admitting the sample into the sensing chamber, and a reagent disposed on a support, the support selected from the group consisting of at least one wall of the electrochemical cell, an independent support, and a self support wherein the device contains a quantity of the reagent sufficient for only a single test, and capable of undergoing a redox reaction directly with the analyte to generate an electrical signal indicative of the presence or absence of the analyte. Diebold does not teach or even suggest applicant's claimed device.

In particular, Diebold fails to teach or even suggest a device in which the reagent is disposed on a support, the support selected from the group consisting of at least one wall of the electrochemical cell, a wall of the sensing chamber, an independent support, and a self support. In contrast, Diebold clearly teaches that the reagent is applied to the working electrode, the reference electrode, or the counter electrode. (See Diebold at col. 10, lines 14-29.) In Diebold, the capillary chamber is merely used to catch reagent and prevent it from spilling into the patient's open wound and contaminating the wound when a test is performed using the patient's finger, it is not involved in the support of any reagent. (See Diebold at col. 10, lines 31-34.)

Therefore, claim 1, and claims 2-20 which depend therefrom, distinguish over Diebold and represent allowable subject matter.

**Claim Rejections- 35 U.S.C. § 103(a)**

The Examiner rejects dependent claims 7, 13 and 17 under 35 U.S.C. § 103(a) as obvious over Diebold in view of U.S. Patent No. 5,120,420 of Nankai et al. ("Nankai"). The Examiner argues that Diebold discloses the claimed invention *except for* use of a reference electrode in addition to the first and second electrodes, the use of buffer solutions, and specification of the distance between the first and second electrodes. The Examiner relies on Nankai to repair these deficiencies. Applicant respectfully disagrees.

Applicant respectfully submits that neither Diebold nor Nankai teach or even suggest that the reagent is disposed on a support, the support selected from the group consisting of at least one wall of the electrochemical cell, a wall of the sensing chamber, an independent support, and a self support as recited in applicant's amended claim 1.

Accordingly, dependent claims 7, 13 and 17 distinguish over diebold and Nankai, taken alone or combined. Therefore, applicant respectfully request that the Examiner reconsider and withdraw this rejection.

**CONCLUSION**

In view of the reasons set forth above, each of the presently pending claims in this application is believed to be in condition for allowance, and reconsideration is respectfully

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requested. The Examiner is urged to telephone the undersigned Attorney for Applicant in the event that such communication is deemed to expedite prosecution of this matter.

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Respectfully submitted,

By 

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